DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Richard Wolf Medical Instruments Corp.
Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K011496
Trade/Device Name: Cysto-Urethroscope "E-Line" and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Dated (Date on orig SE ltr): May 14, 2001
Received (Date on orig SE ltr): May 15, 2001

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of August 10, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K011496

Device Name: Cysto-Urethroscope 'E-Line' and Acessories

Intended Use: The Cysto-Urethroscopes 'E-Line' and Accessories are used to visualize and manipulate the bladder, urethra and ureter via natural passages.

The **sheath** is used to house the endoscope, inserts, and attachments. The sheath provides irrigation, water supply and drainage.

The **obturator/viewing obturator** serves to insert the sheaths atraumatically. If a viewing obturator is used, the insertion can be observed.

The **inserts** are used to guide and angle flexible auxiliary instruments.

The **attachments** (adapters) serve to connect endoscope and sheath.

The **forceps/optical forceps and scissors** are used for endoscopically controlled grasping, manipulating, cutting, dissecting and removal of tissue, bladder stones and foreign bodies via natural and surgically created passages.
Optical forceps with unipolar HF connections are used for coagulation by means of high frequency currents to treat minor hemorrhages.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011496

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter ____

K011496

AUG 1 0 2001

RICHARD WOLF
Medical Instruments Corporation

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: May 14, 2001
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Cysto-Urethroscopes "E-Line", existing of: Sheaths, Obturators, Inserts, Attachments, and Forceps	Model number: 8650.xxx,8652.xxx, 8660.xxx.....see section 4: 'submitted devices'
Common name: Cysto-Urethroscopes and accessories	**Classification Name:** Cysto-Urethroscopes and accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-amend.	1 Cysto-Urethroscopes	1 Richard Wolf
2 K980302	2 Resectoscopes, Instruments and Accessories E-Line	2 Richard Wolf

1.0 Description

The Cysto-Urethroscopes "E-Line" submission consists of Sheaths, Obturators, Inserts, Adapters and Optical Forceps.

2.0 Intended Use

The Cysto-Urethroscopes "E-Line" and Accessories are used to visualize and manipulate bladder, urethra and ureter via natural passages.

The **sheath** is used to house the endoscope, inserts, and attachments. The sheath provides irrigation, water supply and drainage.

The **obturator/viewing obturator** serves to insert the sheaths atraumatically. If a viewing obturator is used, the insertion can be observed.

The **inserts** are used to guide and angle flexible auxiliary instruments.

The **attachments** (adapters) serve to connect endoscope and sheath.

The **forceps/optical forceps and scissors** are used for endoscopically controlled grasping, manipulating, cutting, dissecting and removal of tissue, bladder stones and foreign bodies via natural and surgically created passages.
Optical forceps with unipolar HF connections are used for coagulation by means of high frequency currents to treat minor hemorrhages.

3.0 Technological Characteristics

The submitted Cysro-Urethroscopes " E-Line" are equivalent in function and intended use/indication to pre-amendment devices. They are optimized and improved in dimensions and material due to technical progress. They have a modern ergonomic design "E-Line" same a Resectoscope "E-Line", cleared in pre-market notification K980302.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to pre-amendment devices and to existing devices (K980302) sold by Richard Wolf.

5.0 Performance Data

The submitted devices are in conformance with the relevant provisions of the Medical Device Directive 93/42/EEC. This are pending approval by a conformity assessment procedure according to Annex II and VII.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Aug 1, 2001

Robert L. Casarsa
Quality Assurance Manager